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MERIDIAN MEDICAL

610 Newport Center Drive, Suite 1050
Newport Beach, CA 92660

SUMMARY

Submitter's name:	Meridian Medical
Address:	610 Newport Center Drive, Suite 1050 Newport Beach, CA 92660
Phone:	949-718-9220
Fax number:	949-718-9234
Name of contact person:	*Greg Holland* Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821 greg@regulatoryspecialists.com
Date the summary was prepared:	July 31, 2003
Name of the device:	FEP and Stylo
Trade or proprietary name:	FEP and Stylo
Common or usual name:	External fixation systems
Classification name:	Invasive traction component (per 21 CFR section 888.3040)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

FEP Predicate

K#	Device Name	Manufacturer
K952730	Hoffman II External Fixation System	Howmedica

Stylo Predicate

K#	Device Name	Manufacturer
K831576	Orthofix	Orthofix

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Description of the device:

The FEP and Stylo external fixation systems, are modular systems with the components of: joints, bars, clamps or screws. Such components, with various assemblies, form a device indicated for reconstruction and corrections of bone segments of the human body. All components are made of either Aluminum alloy 7012 or Stainless steel, AISI 316LVM, ISO 5831-1/9.

Intended use of the device:

The FEP and Stylo external fixation systems, are modular systems with the components of: joints, bars, clamps or screws. Such components, with various assemblies, form a device indicated for reconstruction and corrections of bone segments of the human body.

Summary of the technological characteristics of our device compared to the predicate device:

As can be seen in the Comparison section, the Meridian Medical devices and the Howmedica devices have similar technological characteristics, the same design and materials and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Meridian Medical
c/o Mr. Greg Holland
Regulatory Consultant to Meridian Medial
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, CA 92606

Re: K032427
Trade/Device Name: FEP and Stylo
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: August 4, 2003
Received: August 6, 2003

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032427

Device Name: FEP and Stylo

Indications For Use:

The FEP and Stylo external fixation systems, are modular systems with the components of: joints, bars, clamps or screws. Such components, with various assemblies, form a device indicated for reconstruction and corrections of bone segments of the human body.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032427